

Remarks

Claims 14-18, 20-23, and 25-28 are currently pending in the present application.

Drawings

A copy of corrected drawings (Figs. 1-7), sent under separate cover to the Draftsperson, is enclosed for the Examiner's review.

112 Rejection - Enablement

Claims 14-18, 20-23 and 25-28 have been rejected under 35 USC 112 for failing to comply with the enablement requirement. The Examiner specifically objects to the Applicants exemplifying the herbicide resistant properties of the claimed EPSPS mutants in bacteria (*Salmonella typhi*) instead of plants. The Examiner then goes on to cite *In re* Wands concerning undue experimentation. This rejection is respectfully traversed.

Undue experimentation is not present in the case at hand for the following reasons:

- a. Nature of the Invention: The present invention is a plant biotechnology invention. By its own very definition plant biotechnology inventions take a relatively long time to conduct especially if subsequent generation studies are conducted; relative, to say, a chemical reaction that may take nano-seconds, seconds, minutes or hours to complete and record observations. Plant biotechnology inventions typically involve long periods of tissue culture, cell preparation, transformation or gene repair processes, regeneration and plant growth to maturity and seed collection. If subsequent generation plants are analyzed then the time is increased according to the specific plant's life cycle. "Normal" plant experiments can take years instead of minutes. The "nature of the invention" standard in Wands should acknowledge this fact. It would be unfair and prejudicial to penalize the Applicants just because the time requirements required to do "plant" experiments.
- b. Quantity of Experiments of Experimentation Necessary: The teaching of the present

protein) to be changed. The experiments necessary would involve the preparation of the specific oligonucleotides and the treatment of plant cells with them. Mutated cells would then have to be isolated and regenerated. Second generation plants could also be grown and tested for the mutation. These experiments are standard and routine experiments for one of ordinary skill in the plant biotechnology arts.

- c. Amount of Direction or Guidance Presented. The Specification and Claims are directed specifically to amino acid positions on the EPSPS protein that are required to be changed. You can't get more specific than that. By naming an amino acid position one skilled in the art would be directed to the exact position on the protein and then would know EXACTLY what nucleotides could be changed in the corresponding EPSPS gene to affect the mutation. This is plainly and clearly a roadmap to carry out the invention.
- d. Presence or Absence of Working Examples: There is no requirement that working examples be present in a patent Specification. What the Specification must do is teach how to practice the claimed invention. As noted above there are very clear and concise directions (and claim elements) that teach a skilled artisan how to make the presently claimed mutations. This, combined with the fact that conducting experiments could take several months to a couple of years, is reason NOT to require working examples to meet the Wands test. Therefore, the lack of working examples should not be used against the Applicants.
- e. State of the Prior Art, Skill in the Art and Predictability. All of these considerations will be dealt with together. Gene repair technology was known in the art well before the present application was filed. See, for example, US Patents 5,565,350 (Kmiec '350) filed in 1994 and 5,731,181 (Kmiec '181) filed in 1996. Claims issued in the Kmiec '350 and Kmiec '181 patents are broad in scope compared to the presently pending claims to specific mutations on a specific gene. It is very clear from the prior art that one of ordinary skill in the art had the tools to do gene repair experiments and that specific directions to mutate specific amino acids in a known protein would enable the skilled artism to make the appropriate aligns that would result in said mutations in a year.

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Regarding the scope of the claims bearing a reasonable correlation to the scope of enablement (*In re* Fisher) the above arguments are also applicable. The scope of the present claims is limited to specific mutations which are all listed in the Specification. The claims are not overly broad.

In view of the above arguments it is respectfully requested that the present 112 rejection be withdrawn.

103 Rejection by Kmiec '325 in View of Hawkes et al

Claims 14-18, 20-23 and 25-28 have been rejected under 35 USC 103(a) as being unpatentable over Kmiec '325 in view of Hawkes et al WO 98/54330 published 3 December 1998 and Applicants' admission. This rejection is respectfully traversed.

The presently pending Claims are limited to methods of making specific mutant EPSPS genes in plants. In particular, the EPSPS genes are mutated to result in the expression of an EPSPS gene product (protein) that has a mutation at one or more of the following amino acid positions:

Leu₁₇₃;

Ala₁₇₉,

Met₁₈₀,

 Arg_{181} ,

Ser₉₈,

Ser₂₅₅ and

Leu₁₉₈

in *Arabidopsis* or at an analogous amino acid residue in an EPSPS paralog. Kmiec '325 in combination with Hawkes et al cannot support a 103(a) rejection of the present claims because Kmiec '325 does not specifically teach the mutation of the EPSPS gene in plants and Hawkes et al do not teach changing the amino acids in the EPSPS protein in the presently claimed positions. Additionally, Hawkes et al is totally silent as to the effects that the presently claimed amino acid position mutations would impart on the activity of the EPSPS protein. There is absolutely no teaching in either Kmiec '325 or Hawkes et al regarding the likelihood of success or failure of the

presently claimed mutant EPSPS gene products. Therefore, Kmiec '325 in view of Hawkes et al cannot support an obviousness rejection.

Claims 14-18 and 20-23 and 25-28 are not rendered obvious by Kmiec '325 in view of Hawkes et al. Withdrawal of the 103(a) rejection to Claims 14-18, 20-23 and 25-28 is respectfully requested.

In view of the above it is respectfully requested that all of the pending rejections be withdrawn and that Claims 14-18, 20-23 and 25-28 be allowed to issue.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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